DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1219]

Biological Products; Bacterial Vaccines and Related Biological Products; Revocation of Biologics Licenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of certain biologics licenses. This action was taken at the voluntary request of the licensees in response to a proposed order for the Implementation of Efficacy Review for Bacterial Vaccines and Related Biological Products.

DATES: The revocation of the biologics license for the manufacture of Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency," manufactured by Hollister-Stier Laboratories, LLC, U.S. license 1272, became effective August 3, 2000. The revocation of the biologics license for the manufacture of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, Diphtheria and Tetanus Toxoids Adsorbed, Diphtheria Toxoid Adsorbed, and Tetanus Toxoid Adsorbed, manufactured by BioPort Corp., U.S. license 1260, became effective November 20, 2000. Other products under these licenses are not affected by this revocation.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 15, 2000 (65 FR 31003), FDA issued a proposed order to accept the conclusions and recommendations of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the Panel on

Review of Allergenic Extracts (the Allergenics Panel) concerning the safety, effectiveness, and labeling of certain bacterial vaccines and related biological products that were previously classified into Category IIIA (remaining on the market pending further studies in support of effectiveness). On the basis of the Allergenics Panel and the VRBPAC findings, FDA proposed to reclassify certain Category IIIA products into Category I (safe, effective, and not misbranded) or Category II (unsafe, ineffective, or misbranded). This action was taken under the reclassification review procedures specified in 21 CFR 601.26. The proposed order also announced the agency's intention to revoke the biologics licenses for those bacterial vaccines and related products classified as Category II (unsafe, ineffective, or misbranded).

Certain Category IIIA bacterial vaccines and toxoids with standards of potency listed in the proposed order were classified into two categories based upon their use as a primary immunogen or as a booster. Diphtheria and Tetanus Toxoids Adsorbed, and Tetanus Toxoid Adsorbed manufactured by BioPort Corp. were recommended by the VRBPAC for classification into Category II (unsafe, ineffective, or misbranded) for primary immunization and Category I (safe, effective, and not misbranded) for booster immunization.

Similarly, certain bacterial vaccines and related biological products listed in the proposed order were recommended for classification into Category II for both diagnosis and immunotherapy by the Allergenics Panel. Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency," manufactured by Hollister-Stier Laboratories, LLC, was recommended for classification into Category II for both diagnosis and immunotherapy by the Allergenics Panel.

FDA agreed with the recommendations of the VRBPAC and the Allergenics Panel to reclassify the above cited products into Category II for their respective indications, and in the proposed order provided notice of the agency's intent to revoke the licenses to manufacture these products. On June 19, 2000, Hollister-Stier Laboratories, LLC, submitted a letter to FDA voluntarily requesting revocation of its license to manufacture Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency." On August 9, 2000, BioPort Corp. submitted a letter to FDA voluntarily requesting

revocation of its license to manufacture Diphtheria and Tetanus Toxoids Adsorbed, and Tetanus Toxoid Adsorbed. In its August 9, 2000, letter, BioPort Corp. also voluntarily requested revocation of its license to manufacture Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, and Diphtheria Toxoid Adsorbed, although these products were not included in the proposed order.

The proposed order announced that the agency would publish a notice of opportunity for a hearing on the revocation of the license of each product classified in Category II. BioPort Corp. and Hollister-Stier Laboratories waived their opportunity for a hearing when they voluntarily requested license revocation for their reclassified Category II products.

Accordingly, under the provisions of 21 CFR 601.5(a), section 351 of the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), FDA revoked the biologics license issued to Hollister-Stier, Laboratories, LLC, U.S. license 1272, for the manufacture of Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency," effective August 3, 2000; and FDA revoked the biologics license issued to BioPort Corp., U.S. license

1260, for the manufacture of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, Diphtheria and Tetanus Toxoids Adsorbed, Diphtheria Toxoid Adsorbed, and Tetanus Toxoid Adsorbed effective November 20, 2000.

Dated: 5/09/01
May 9, 2001.

Kathryn C. Zoon,
Director,
Center for Biologics Evaluation and Research.

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